Docket No. 21419 US (C038435/0185660)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)

Tatsuo HOSHINO *et al.*)

Serial No.: 10/528,845)

Filed (U.S.): March 23, 2005)

For: **A GENE ENCODING VITAMIN B_6 PHOSPHATE PHOSPHATASE AND USE THEREOF**)

Examiner: I. H. Chowdhury

Art Unit: 1652

New York, New York
November 21, 2006

RESPONSE TO RESTRICTION REQUIREMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to the Office Action mailed October 23, 2006, which set a one-month shortened statutory period for response. Accordingly, this response is filed timely upon mailing, with an executed certificate of mailing, on or before November 24, 2006 because November 23, 2006 falls on a Federal Holiday. 37 CFR §§ 1.7 and 1.8. No fee is believed to be due. If it is determined that a fee is due, please charge such fee to Deposit Account No. 02-4467. A duplicate copy of this sheet is enclosed.

On page 2 of the Office Action, the Examiner issued a three-way restriction requirement pursuant to 35 USC §§ 121 and 372. (Paper No. 20061004 at 2). The restriction divided the claims into the following allegedly distinct inventions: Group I (claims 1-2, 4-6, 7, 9-10, and 11) "drawn to an isolated polynucleotide encoding a polypeptide vitamin B_6 phosphate phosphatase, vector and recombinant microorganism comprising said gene;" Group II (claim 3) "drawn to isolated polypeptide vitamin B_6 phosphate phosphatase;" and Group III (claims 8 and 12-13) "drawn to a process for producing vitamin B_6 by using cell free extract." (*Id.*).

In making the restriction requirement, the Examiner asserted that "[t]he inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features." (*Id.*). The Examiner further asserted that "[t]he polynucleotide encoding a polypeptide vitamin B6 phosphate phosphatase of Group I and [the] polypeptide vitamin B6 phosphate phosphatase of Group II, [are] each unrelated and chemically distinct entities. The only shared technical feature of these groups is that they all relate to [a] polynucleotide encoding a polypeptide vitamin B6 phosphate phosphatase. However, this shared technical feature is not a 'special technical feature' as defined by PCT Rule 13.2 as it does not define a contribution over the art." (*Id.* at 2-3).

The Examiner's *sole* basis for concluding that there is no special technical feature is a GenBank citation (Accession No. AL591783) identified on the International Search Report (copy attached as Exhibit 1). According to the Examiner, AL591783 discloses "a DNA encoding vitamin B6 phosphate phosphatase ...." (*Id.* at 3). And,

also according to the Examiner, the PCT search report discloses that "a DNA encoding vitamin B6 phosphate phosphatase is known in the art" based on AL591783. (*Id.*) (internal citation omitted). In view of the foregoing, the Examiner concluded that "a DNA encoding a vitamin B6 phosphate phosphatase protein does not make [a] contribution over the prior art" and, thus, there is no unity of invention (*Id.*).

For the reasons set forth below, the restriction requirement is respectfully traversed.

Initially, we note that the Examiner must apply the so-called "unity of invention" rules set forth in PCT Rules 13.1 and 13.2. *See, e.g.*, 37 CFR § 1.499 and MPEP §1893.03(d) at 1800-199-200 (Rev. 5, August 2006). PCT Rule 13.2 states:

> Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean **those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art**. (Emphasis added).

The MPEP further counsels Examiners to consult "the examples contained in Chapter 10 of the International Search and Preliminary Examination Guidelines which can be obtained from WIPO's web site (www.wipo.int/pct/en/texts/gdlines.htm)." (MPEP §1893.03(d) at 1800-200). Of particular relevance here is Example 39 entitled "Protein and its Encoding DNA." (*See*, PCT/GL/ISPE/1,§10.59, p. 96 (March 11, 2004) (copy attached as Exhibit 2)). Like the

Example 39 claims, claims 1 (Group I) and 3 (Group II) of the present invention recite "isolated DNA" and a polypeptide [protein] encoded by the isolated DNA, respectively.

The Guidelines state with respect to Example 39:

> The claimed DNA molecule encodes protein X, and therefore protein X and the DNA encoding protein X share a corresponding technical feature. Consequently, the claims have unity of invention (*a priori*).
>
> ***Because protein X makes a contribution over the prior art, protein X and the DNA encoding protein X share a special technical feature***. (*Id.*)

Thus, the Examiner's conclusion is directly in conflict with the Guidelines. The Examiner's conclusion, however, *cannot* be supported by reliance on the International Search Report and is in direct conflict with the International Preliminary Examination Report. In short, the Examiner's conclusion is based *solely* on the unsupported allegation that a GenBank entry, which was before the IPEA, somehow renders the claimed polypeptide unpatentable:

> According to the search report (PCT form 210), a DNA encoding a vitamin B6 phosphate phosphatase ***is known in the art*** (GenBank Accession No. AL591783 created 8/1/2001). Thus a DNA encoding a vitamin B6 phosphate phosphatase protein does not make [a] contribution over the prior art. (Paper No. 20061004 at 3).

The deficiencies with this argument are myriad. First, the Examiner fails to identify where in AL591783 it is disclosed that the translation product defined by the polynucleotide sequence encodes "a vitamin B6 phosphate phosphatase." Second, the Examiner does not - and cannot - identify where in the search report it is stated, or even suggested, that "a DNA encoding a vitamin B6 phosphate phosphatase is known in the

art." Indeed, the Examiner's conclusion is in direct conflict with the IPER, which had AL591783 before it: "The present application relates to a vitamin B6 phosphate phosphatase ... ***which has not been disclosed before in the prior art***." (emphasis added) (Form PCT/Separate Sheet/409 (Sheet 1)); *see also* Form PCT/PEA/409 (concluding that all claims have novelty, inventive step, and industrial applicability). In view of the foregoing, the lack of unity of invention conclusion with respect to Groups I and II cannot stand and must be withdrawn.

For essentially the same reasons, it is respectfully submitted that the Examiner's conclusion with respect to Groups II and III is factually and legally deficient and must be withdrawn also. In this regard, we note that the process recited in claim 8 refers back to the DNA of claim 1 (through claim 4). Again, the Examiner fails to explain how the "cell free extract" recited in, *e.g.*, claim 8 does not utilize a polypeptide as recited in claim 3 (*i.e.*, "[a] polypeptide encoded by the isolated DNA of claim 1"). We further note that the Examiner failed to even conduct a unity of invention analysis with respect to Groups I and III. Thus, the Examiner's conclusion with respect to Groups II and III is not well taken.

In sum, it is respectfully submitted that the Examiner's conclusion with respect to the lack of unity between Groups I and II and Groups II and III is factually and legally deficient and must be withdrawn.

Although unnecessary in light of the foregoing, in accordance with restriction practice, the subject matter of claims 1-2, 4-6, 7, 9-10, and 11 (Group I) is hereby provisionally elected for prosecution, with traverse, to satisfy the requirements of 37 CFR § 1.143.

If the Examiner has any questions regarding this paper, please contact the undersigned attorney.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450, on November 21, 2006.

Charles M. Avigliano

Charles M. Avigliano, Reg. No. 52,578

Respectfully submitted,

By: Charles M. Avigliano

Charles M. Avigliano
Registration No. 52,578
BRYAN CAVE LLP
1290 Avenue of the Americas
New York, NY 10104
Phone: (212) 541-2000
Fax: (212) 541-4630

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION** see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
Case 21419		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/EP 03/10575	23/09/2003	27/09/2002
Applicant		
ROCHE VITAMINS AG		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [X] contained in the international application in written form.

   [X] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [X] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [X] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. _____

   [ ] as suggested by the applicant.

   [ ] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

   [X] None of the figures.

I ERNATIONAL SEARCH REPORT

International Application No
PCT/EP 03/10575

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 C12N15/55 C12N9/16 C12P17/12 C12N1/21

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 C12N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
SEQUENCE SEARCH, EPO-Internal, WPI Data, PAJ, BIOSIS, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 03 000875 A (ROCHE VITAMINS AG ;TAZOE MASAAKI (JP); HOSHINO TATSUO (JP); ICHIKA) 3 January 2003 (2003-01-03) page 8 -page 10; claims 1-15 ---	3
A	DATABASE EBI 'Online! 5 July 2002 (2002-07-05) Database accession no. AL591783; AL591688 XP002275874 cited in the application abstract ---	
A	EP 0 950 715 A (HOFFMANN LA ROCHE) 20 October 1999 (1999-10-20) the whole document ---	
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
1 April 2004	21/04/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Schneider, P

1

Form PCT/ISA/210 (second sheet) (January 2004)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	TAZOE M ET AL: "PRODUCTION OF VITAMIN B6 IN RHIZOBIUM" BIOSCIENCE BIOTECHNOLOGY BIOCHEMISTRY, JAPAN SOC. FOR BIOSCIENCE, BIOTECHNOLOGY AND AGROCHEM. TOKYO, JP, vol. 63, no. 8, August 1999 (1999-08), pages 1378-1382, XP008026955 ISSN: 0916-8451 ---	
A	TAZOE M ET AL: "Biosynthesis of vitamin B6 in Rhizobium" JOURNAL OF BIOLOGICAL CHEMISTRY, AMERICAN SOCIETY OF BIOLOGICAL CHEMISTS, BALTIMORE, MD, US, vol. 275, no. 15, 14 April 2000 (2000-04-14), pages 11300-11305, XP002221306 ISSN: 0021-9258 ---	
A	YANG YONG ET AL: "Involvement of the gapA- and epd (gapB)-encoded dehydrogenases in pyridoxal 5'-phosphate coenzyme biosynthesis in Escherichia coli K-12" JOURNAL OF BACTERIOLOGY, WASHINGTON, DC, US, vol. 180, no. 16, August 1998 (1998-08), pages 4294-4299, XP002266176 ISSN: 0021-9193 -----	

ERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/EP 03/10575

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 03000875 A	03-01-2003	CA 2449378 A1	03-01-2003
		WO 03000875 A2	03-01-2003
		EP 1397487 A2	17-03-2004
EP 0950715 A	20-10-1999	EP 0950715 A2	20-10-1999
		AU 2372799 A	28-10-1999
		BR 9902362 A	06-06-2000
		CA 2268539 A1	15-10-1999
		CN 1232875 A	27-10-1999
		ID 22473 A	21-10-1999
		JP 2000023690 A	25-01-2000
		NO 991738 A	18-10-1999
		US 6060267 A	09-05-2000

One possible grouping would be:

Invention 1: Method to identify compounds... (claim 1)

Invention 2: Compound X (claim 2)

Invention 3: Compound Y (claim 3)

Invention 4: Compound Z (claim 4)

[redacted]

Claim 1: Isolated protein X having SEQ ID NO: 1.

Claim 2: Isolated DNA molecule encoding protein X of claim 1.

(Some Authorities presume that a claimed biological molecule is in isolated form and therefore do not require the claim to explicitly include the term "isolated" as above.)

The disclosure teaches that protein X is an interleukin-1, a soluble cytokine involved in the activation of lymphocytes. The disclosure also sets forth a DNA molecule having SEQ ID NO: 2 that encodes SEQ ID NO: 1.

There is no prior art.

The claimed DNA molecule encodes protein X, and therefore protein X and the DNA encoding protein X share a corresponding technical feature. Consequently, the claims have unity of invention (*a priori*).

Because protein X makes a contribution over the prior art, protein X and the DNA encoding protein X share a special technical feature.

If an alternative DNA claim was presented that encompassed a DNA molecule that did not encode protein X, some Authorities might find that the claims did not share the same or corresponding technical feature and therefore lacked unity. Examples of such a claim follow:

Isolated DNA molecule encoding protein X, or a DNA fragment thereof.

Isolated DNA molecule having SEQ ID NO: 2, or DNA molecules which hybridise to SEQ ID NO: 2 under stringent conditions.

If prior art existed teaching either protein X or the DNA encoding protein X, some Authorities might find that the same or corresponding technical feature did not make a contribution over the prior art, that is, was not a special technical feature, and therefore unity was lacking (*a posteriori*).

Process at the International Search Stage

Invitation to Pay Additional Fees

Article 17(3)(a); Rules 16, 40.2, 40.3, 42

10.60 After deciding that lack of unity exists, except in the circumstances described in paragraphs 10.64 and 10.65, the International Searching Authority informs the applicant of the lack of unity of invention by a communication, preceding (but see paragraph 10.61, below) the issuance of the international search report and written opinion of the International Searching Authority, which contains an invitation to pay additional fees (Form PCT/ISA/206). This invitation specifies the reasons (see paragraph 10.63) for which the international application is not considered as complying with the requirement of unity of invention, identifies the separate inventions and indicates the number of additional search fees and the amount to be paid. The International Searching Authority cannot consider the application withdrawn for lack of unity of invention, nor invite the applicant to amend the